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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,034	08/18/2000	David Mack	A-69195/RMS/DAV/JJD	6513

7590 12/10/2001
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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

5

DATE MAILED: 12/10/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/642,034

Applicant(s)

MACK ET AL.

Examiner

Padmavathi v Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, drawn to a method of screening drug candidate comprising determining the effect of drug on the expression of profile gene encoding BCR4, classified in class 435, subclass 6.
 - II. Claims 3-4, drawn to a method of screening for a bioreactive agent capable of binding to BCR4, classified in class 435, subclass 4.
 - III. Claim 5-6, drawn to a method of evaluating the candidate breast cancer drug for a bioreactive agent capable of binding to BCR4, classified in class 514, subclass 44.
 - IV. Claim 7, drawn to a method diagnosing breast cancer, classified in class 435, subclass 6.
 - V. Claims 8-13, drawn to an antibody, classified in class 424, subclass 133.1.
 - VI. Claims 14-15, drawn to a method of screening for a bioreactive agent capable of interfering with the binding to BCR4, classified in class 435, subclass 7.2.
 - VII. Claims 16-17, drawn to a method for inhibiting the activity of BCR4, classified in class 435, subclass 7.6.
 - VIII. Claim 18, drawn to a method for neutralizing the effect of BCR4, classified in class 435, subclass 7.1.
 - IX. Claims 19-20 drawn to a method of treating breast cancer, classified in class 424, subclass 130.1.

Art Unit: 1645

- X. Claims 21-23 drawn to a method of exposing therapeutic moiety of breast cancer, classified in class 436, subclass 542.
- XI. Claims 24-26 drawn to a method of treating breast cancer using antibody, classified in class 424, subclass 7.11.
- XII. Claim 27, drawn to a method for inhibiting breast cancer, classified in class 536, subclass 24.5
- XIII. Claim 28, drawn to a biochip comprising nucleic acid segment, classified in class 536, subclass 23.1.
- XIV. Claim 29, drawn to a method of eliciting an immune response comprising antigen, classified in class 434, subclass 184.1.
- XV. Claim 30, drawn to a method of eliciting an immune response comprising nucleic acid encoding antigen, classified in class 514, subclass 44.
- XVI. Claim 31, drawn to a method-determining prognosis with breast cancer, classified in class 204, subclass 450.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions V and XIII are different products which are patentably distinct products structurally, functionally and biochemically. Invention XIII is drawn to biochip comprising nucleic acid segments which contain nucleic acids. Invention V is drawn to an antibody which contain amino acids and indistinct from Invention XIII since it has an inherent affinity, avidity, and specificity which a nucleic acid chip does not contain.

3. Inventions I-IV, VI-XII, and XIV-XVIII are drawn to patentably distinct methods which require different reagents, steps and result in a different outcome. For Example, invention I utilizes candidate drug compounds and cells expressing BCR4 profile gene where as invention XIV requires antigen and an animal in order to induce immune response.

Art Unit: 1645

4. Inventions V and I-IV/VI-XII /XIV-XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as immunochromatography for purifying antigens.
5. Inventions XIII and I-IV/VI-XII /XIV-XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as making hybrid compounds.
6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1645

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmavathi v Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on M-F (6:30A.M-4: 00 P.M.) First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

P. Baskar Ph.D
12/8/01

Padmavathi v Baskar
12/10/01